K002764

NOV 2 4 2000

HYDROCISION, INC.
100 Burtt Rd
Suite G01
Andover, MA 01810

510K Summary

1. Sponsor Name
   HydroCision, Inc
   100 Burtt Rd. Suite G01
   Andover, MA 01810
   Telephone: 978 474-9300
   Contact Individual: Debbie Iampietro

2. Device Name
   Proprietary Name: HydroCision ArthroJet System with Cautery and Burr
   Common/Usual Name: Surgical Instrument Motors and Accessories
   Classification Name: Arthroscope and Accessories
   Surgical Instrument Motors and Accessories
   Bone cutting instruments and accessories

3. Identification of Predicate or Legally Marketed Device
   The HydroCision ArthroJet System with Cautery and Burr is substantially equivalent in intended use and/or function to the following predicate devices: the HydroCision ArthroJet with Cautery, the Smith and Nephew Dyonics Burrs, the Hall Ototome Drill Systems and the Linvatec E9000 System.

4. Device Description
   The HydroCison ArthroJet System with Cautery and Burr consists of the reusable power control unit; bipolar cables; and a sterile, disposable pump cartridge, handpiece and tubing assembly. It provides the same functions as the predicate upon which it is based (HydroCision ArthroJet with Cautery K993099) including cutting, evacuation, and electrocauterization. A handpiece modification in the HydroCision ArthroJet System with Cautery and Burr is designed to provide the additional functions of cutting, drilling, reaming, decorticating, and smoothing of bone. The handpiece includes the rotating burr, which is driven by a liquid-jet driven rotor. It is also available with a variety of burrs and drills.

5. Intended Use
   The intended use of the HydroCision ArthroJet System with Cautery and Burr is for orthopedic surgical procedures in which the cutting and removal of soft and hard tissue or bone is needed and the control of bleeding during these procedures. Specific functions include cutting, ablation, drilling, reaming,

decorticating and smoothing of bone and other bone related tissue in a variety of surgical procedures including open and arthroscopic spinal surgeries and small and large joint arthroscopic procedures.

6. Comparison of Technological Characteristics

The HydroCision ArthroJet System with Cautery and Burr is a surgical device which adds cutting, drilling, reaming, decorticating, and smoothing of bone and other bone related tissue to the functions of the FDA cleared ArthroJet with Cautery. It is substantially equivalent in intended use and/or function to the following predicate devices: the HydroCision ArthroJet with Cautery, the Smith and Nephew Dyonics Burrs, the Hall Ototome Drill Systems and the Linvatec E9000 System.

The components of the HydroCision ArthroJet System with Cautery and Burr and predicate systems are the same, however the method of conveying power to drive the respective handpieces is different. All of predicates include a control unit, handpiece, and footswitch. Two of the predicates drive the handpieces with electric power. The HydroCision predicate and the HydroCision ArthroJet System with Cautery and Burr are pressure driven by water. The HydroCision ArthroJet System with Cautery and Burr provides an electrocauterization function at the distal tip of the handpiece, the same as the HydroCision predicate.

7 Performance Testing

Prior to marketing, the HydroCision ArthroJet System with Cautery and Burr will comply with the following standards for performance:

ANSI/AAMI HF 18-1993
IEC 60601-1
IEC 60601-1-2

The HydroCision ArthroJet System with Cautery and Burr was performance tested and compared with the predicate Smith & Nephew EP-1 shaver system.

The objective of the tests was to quantify the rate of bone removal for the HydroCision ArthroJet System with Cautery and Burr and compare that with the rate of bone removal for the predicate Dyonics (Smith & Nephew) EP-1 shaver system, utilizing an identical bone burr.

Results of the tests demonstrated that the HydroCision ArthroJet System with Cautery and Burr performed equal to or better than the predicate Dyonics EP-1 System in bone removal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2000

HydroCision, Inc.
c/o Ms. Debbie Iampietro
QRC Consulting
7 Tiffany Trail
Hopkinton, Massachusetts 01748

Re: K002764
Trade Name: HydroCision ArthroJet System with Cautery and Burr
Regulatory Class: II
Product Code: HRX
Dated: September 1, 2000
Received: September 5, 2000

Dear Ms. Iampietro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002764

Device Name: HydroCision ArthroJet System with Cautery and Burr

Indications For Use:

The HydroCision ArthroJet System with Cautery and Burr is indicated for orthopedic surgical procedures where the cutting and removal of soft and hard tissue or bone and control of bleeding during those procedures is needed. Specific functions include cutting, ablation, drilling, reaming, decorticating and smoothing of bone and other bone related tissue in a variety of surgical procedures including open and arthroscopic spinal surgeries and small and large joint arthroscopic procedures.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milburn

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002764

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)